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What is This?
Feasibility, safety and preliminary evidence of the effectiveness of a home-based exercise programme for older people with Alzheimer’s disease: a pilot randomized controlled trial

Plaiwan Suttanon1,2,3, Keith D Hill2,4, Catherine M Said5,6, Susan B Williams2, Karin N Byrne7, Dina LoGiudice8, Nicola T Lautenschlager9 and Karen J Dodd1

Abstract

Objective: To evaluate the feasibility and safety of a home-based exercise programme for people with Alzheimer’s disease, and to provide preliminary evidence of programme effectiveness in improving balance and mobility and reducing falls risk.

Design: A randomized controlled trial.

Setting: Community.

Participants: Forty people with mild to moderate Alzheimer’s disease (mean age 81.9, SD 5.72; 62.5% female).

Interventions: Participants were randomized to a six-month home-based individually tailored balance, strengthening and walking exercise programme (physiotherapist) or a six-month home-based education programme (control) (occupational therapist). Both programmes provided six home-visits and five follow-up phone calls.

Main measures: Balance, mobility, falls and falls risk were measured at baseline and programme completion. Intention-to-treat analysis using a generalized linear model with group allocation as a
predictor variable was performed to evaluate programme effectiveness. Feasibility and adverse events were systematically recorded at each contact.

**Results:** Fifty-eight per cent of the exercise group finished the programme, completing an average of 83% of prescribed sessions, with no adverse events reported. Functional Reach improved significantly ($P = 0.002$) in the exercise group (mean (SD), 2.28 (4.36)) compared to the control group (–2.99 (4.87)). Significant improvement was also observed for the Falls Risk for Older People – Community score ($P = 0.008$) and trends for improvement on several other balance, mobility, falls and falls risk measures for the exercise group compared to the control group.

**Conclusions:** The exercise programme was feasible and safe and may help improve balance and mobility performance and reduce falls risk in people with Alzheimer’s disease.

**Keywords**
Balance and strengthening exercise, falls risk, Alzheimer’s disease, randomized controlled trial

**Introduction**

Falls are common in older people, with one in three community-living people aged over 65 falling each year.\(^1\) Falls are an even greater problem for older people with dementia, with 40–80% of people with dementia falling each year.\(^2\) Consequences of falls are also more serious for people with dementia, with around 60% of those injured sustaining a fracture.\(^3\) There is evidence of accelerated deterioration in physical performance, especially balance and mobility, in people with dementia, including people with Alzheimer’s disease.\(^4\) This deterioration is likely to be a key factor for the increased risk of falls observed in this population.\(^5\)

A recent Cochrane review\(^6\) reported a number of single-factor interventions (such as exercise, cataract extraction, psychotropic medication review) and multifactorial interventions (a combination of single interventions, based on an individual person’s identified risk of falling) that have reduced falls in community-dwelling older people, including those with high falls risk. However, most of the randomized controlled trials in the Cochrane review excluded participants if they had cognitive impairment. Only one randomized controlled trial using a multifactorial falls prevention intervention has been conducted in people with cognitive impairment who presented at emergency departments after a fall. That study reported that a combination of medication review, optical correction, postural hypotension treatment, three-month home-based exercise, and home hazard modification was unsuccessful in reducing falls in these patients.\(^7\) As such, there is little evidence to guide falls prevention practice for people living in the community with dementia.\(^8\)

There is some evidence that exercise programmes are feasible in people with dementia, and may lead to improved physical performance outcomes.\(^5\) However, there is limited evidence that exercise can improve balance or reduce falls rates in this population. A recent systematic review\(^9\) identified only seven published randomized controlled studies evaluating the effectiveness of exercise, that included balance training, and reported balance performance or falls-related outcomes in older people with dementia.

Differences in either form (i.e. group or individual programme), or setting (i.e. care facilities, community setting or home) are expected to influence both feasibility and adherence to the exercise programme. Evidence of the safety and feasibility of an individualized exercise programme delivered at home for community-dwelling older people with dementia is still limited.

Most studies reported in the previous systematic review\(^9\) had mixed or poorly defined samples in terms of the participants’ diagnoses of dementia.
Differences in the underlying aetiology associated with the different types of dementia may result in variable cognitive or physical limitations and so variable responsiveness to interventions. As Alzheimer’s disease is one of the most common forms of dementia, there is a need for studies to investigate the effect of exercise interventions that specifically target people with Alzheimer’s disease.

Given these considerations, the aim of this pilot study was to investigate the feasibility and safety of a home-based exercise programme that focused on balance, strengthening and walking exercises, and to provide preliminary evidence of the effect of the programme on falls and physical performance in community-dwelling older people with mild to moderate Alzheimer’s disease.

Methods

The study was a single-blind randomized controlled trial. The study protocol was approved by the relevant University and Health Services Human Research Ethics Committees. Written informed consent was obtained from participants or their next of kin or caregivers. The trial was registered with the Australian and New Zealand Clinical Trial Register (trial number ACTRN 1260800040369).

Participants with Alzheimer’s disease were recruited through Memory Clinics at two large metropolitan hospitals, community groups providing support for people with Alzheimer’s disease and through public notices in newspapers. Participants were eligible for the study if they had a diagnosis of Alzheimer’s disease confirmed from specialist or Memory Clinic assessment, if the Alzheimer’s disease symptoms were of mild to moderate severity (Mini-Mental State Examination score ≥10) and if they could walk outdoors with no more support than a single-point stick. Participants were also living in the community, and had no other serious orthopaedic condition (e.g. recent lower limb surgery, severe lower limb arthritis) or major neurological disorder (e.g. stroke, Parkinson’s disease) that could potentially restrict functional mobility.

Participants were allocated to either a balance and strengthening home exercise or an education (control) programme, using a concealed randomization procedure. A random numbers table with group allocation was computer-generated by one of the research team (KH) who was not involved in assessments or interventions. These allocations were placed in opaque sealed envelopes. Following baseline assessment, the next numbered envelope was opened by another researcher (SW) who took no part in the assessments, and the participant was then contacted by the therapist (SW or KB) and informed of their group allocation.

Participants in both groups continued with usual care and other activities while participating in their allocated programme.

The home-based exercise programme

Participants randomized to the exercise programme were provided with a six-month individualized home-based exercise programme supervised by a physiotherapist. The programme included standing balance and strengthening exercises and a graduated walking programme and was based on an existing home exercise programme (the Otago Program, www.acc.co.nz/preventing-injuries/at-home/older-people/information-for-older-people/otago-exercise-program/index.htm). The Otago Program has been shown to be effective in reducing falls in older people without cognitive impairment. The total number of home visits by the physiotherapist was increased from four visits (as described in the original randomized controlled trial conducted to evaluate the Otago Program) to six visits. This provided increased support throughout the six-month duration, and maximized the participants’ and caregivers’ understanding of the exercises and of safety issues, particularly during the early phase of the programme. Each participant also received an exercise booklet with illustrations and instructions, and was encouraged to complete the exercises five times a week.

At the first visit, the physiotherapist selected and modified exercises from the Otago Program to address the individual’s balance and mobility problems as identified in the baseline balance and mobility assessment. At each subsequent home visit, the physiotherapist monitored and modified the
exercise programme as required, and answered any questions. Caregivers were also instructed regarding the exercise programme and asked to encourage regular (five days/week) and correct performance of the exercises. Follow-up phone calls by the physiotherapist in between visits were also provided to offer reassurance, to enquire if there were any negative effects from the exercises (such as falling or other physical injuries) and to answer questions about the exercises (five phone calls over the six-month period). The participants and their caregivers were also provided with the physiotherapist’s contact telephone details and were told that they should contact the physiotherapist if they had any questions or concerns about the programme.

Data on exercise adherence were collected using monthly exercise recording sheets completed by participants (with assistance of their caregivers). These were retrieved and reviewed by the physiotherapist at each home visit. Factors limiting participation were explored and recorded by the physiotherapist at each visit. The physiotherapist systematically recorded any accidents or injuries during the exercise interventions at each visit and phone call.

Control (education) programme

The control programme was designed to provide the same number of home visits and phone calls as the exercise programme. It consisted of education and information sessions on the topic of dementia and ageing that were not anticipated to influence the primary physical performance outcomes of the study. The education and information programme was delivered by an occupational therapist, and was based in part on a previously reported home-based education and support programme for people with mild to moderate Alzheimer’s disease, with fair to excellent retest reliability. All measurements were taken by the same assessor who was blind to group assignment. Measures used at baseline to describe the sample and the outcome measures have been detailed in a previously published protocol paper, so are reported in brief here.

The Mini-Mental State Examination, the Frontal Assessment Battery and the Assessment of Quality of Life were used to assess cognition, behavioural disturbance and quality of life respectively.

The number of falls in the preceding 12 months (self-report, based on information from the participant and caregiver) was also recorded at baseline to calculate the rate of falls/1000 person days. In this study, a fall was defined as ‘inadvertently coming to rest on the ground, floor, or other lower level,
excluding intentional change in position to rest in furniture, wall or other objects. A fall may or may not have resulted in physical injury.

Laboratory measures of balance and mobility were undertaken on the NeuroCom Balance Master (long plate) (NeuroCom Balance Master Operator V3), and are reported in detail elsewhere. Assessments used in this study were as follows:

- Modified Clinical Test of Sensory Interaction of Balance – a composite (average) score of sway velocity (degrees/second) for all conditions was reported.
- Limits of stability – composite scores reported included reaction time (seconds), movement velocity (degrees/second), maximum excursion (% of limits of stability boundary) and directional control (%).
- Walk across test, with measures of step width (cm), step length (cm) and walking speed (cm/second) as the participant walked at comfortable speed across the long plate.
- Step/quick turn – average turn time (seconds) and turn sway (degree/second) were reported for both left and right directions, and the worse direction average scores were used for analyses.
- Sit to stand – rising index (%body weight) and centre of gravity sway velocity (degrees/second) were measured.

Four commonly used clinical measures of balance and mobility and one questionnaire evaluating level of physical activity were included. These were:

- Functional Reach test;
- Step Test (performance on the side with a poorer score was recorded);
- Timed Chair Stands;
- Timed Up and Go Test (single task) plus Timed Up and Go Test with a secondary cognitive task (counting backwards by threes while performing the task) and Timed Up and Go Test with a secondary motor task (carrying a full cup of water while performing the task); and
- the Human Activity Profile a measure of physical activity level. The Adjusted Activity Score (AAS) was reported in this study.

Measures of falls and falls risk consisted of the following:

- Incidence rate of falls presented as falls rate/1000 person days. The rate calculated from the number of falls occurring in the time between baseline and follow-up assessment, reported by the participants or caregivers at each of the home visits and follow-up phone calls; and to the assessor at the re-assessment.
- Falls Risk for Older People – Community version, a questionnaire evaluating 13 falls risk factors. This study required two modifications to the questionnaire: deletion of the home assessment item (as assessments were not conducted in the home); and the substitution of the Mini-Mental State Examination score for the Abbreviated Mental Test Score. This resulted in a maximum falls risk score of 57 (instead of 60) in this study.
- Physiological Profile Assessment, an abbreviated assessment of falls risk, evaluating standing balance, hand reaction time, knee joint proprioception, visual contrast sensitivity and quadriceps muscle strength.

The following questionnaires were undertaken to evaluate impact of the programmes on caregivers:

- the Zarit Carer Burden Index and
- the Assessment of Quality of Life (AQOL).

**Exercise programme adherence**

Full compliance (100%) was defined as a participant doing the exercises five days a week (information derived from monthly exercise recording sheets). The percentage of adherence was calculated by dividing the sum of participants’ average adherence by the number of participants who completed the programme.

**Statistical analysis**

All analyses were conducted using intention-to-treat. To manage missing data associated with participants dropping out of the study during the six
months intervention, the baseline carry forward method was used.\textsuperscript{29}

To evaluate the effectiveness of the exercise programme compared to the control group over the six-month period, we used generalized linear models (SPSS version 17.0), with group allocation as the factor (predictor) variable. The models also contained baseline performance on the outcome measure as a covariate. A small number of variables that were significantly different between the two groups at the baseline were considered as additional covariates or factors for the first run of each of the models. Derived from the tests of model effects, only variables with a significant level were included as covariates or factors in the final models of the analyses. Each outcome was analysed by a separate model in which the type of model was selected based on the nature of the outcome measure and its distribution (see Appendix, online). To provide further validation because of the possible influence resulting from the methodology of estimating missing values in this small sample size, the analyses were repeated with the data set of complete cases.\textsuperscript{30}

For the incidence rate of falls outcome, an adjusted odds ratio which represents the predicted rate of falls of the exercise group compared to the control group after covariate adjustment was reported as an output result of the model analysis. An adjusted odds ratio was reported for fallers and non-fallers outcome. The odds ratio represents the odds of the event (of their being a faller) for participants in the exercise group compared to the control group after adjustment of covariates. For other outcome measures, $B$ (coefficient) values were reported. $B$ (coefficient) values represent the average values of the outcome measures of the exercise group compared with the control group, after adjusting for the effects of other factors and/or covariate(s) in the models selected for analysis. A negative $B$ value means that the average value of the outcome of the exercise group is lower than the control group.

A power analysis was calculated for the randomized controlled trial,\textsuperscript{16} indicating 80 participants per group would be required for power of 80\% and alpha of 0.05, with effect size of between 0.4 and 0.5 for Step Test and Limits of Stability – Maximum Excursion measures respectively (see protocol paper\textsuperscript{16}). Funding was received from the National Ageing Research Institute to enable a feasibility study of 40 participants to be enrolled in the programme, and for pilot data to be collected. This paper reports results for these 40 participants.

**Results**

Forty participants with Alzheimer’s disease were randomized to the exercise ($n = 19$) or to the control (education) ($n = 21$) group. The flow of participants through the study is shown in Figure 1.

Baseline characteristics for the 40 participants are summarized in Table 1. Participants in the exercise and control programmes were aged 74–93 years and 68–89 years, respectively. Participants in both groups were predominantly female. Participants in the exercise and control programmes were similar on most measures at baseline (Table 2). However, the exercise group had a significantly greater proportion of fallers, poorer mobility (Timed Up and Go Test with dual task condition) and balance (Functional Reach), and lower physical activity level (Human Activity Profile score).

**Intention-to-treat outcome analysis**

Only 11 of the 19 participants in the exercise group completed the programme. Reasons for dropping out included that the caregiver found the effort was excessive (3 participants), the person with Alzheimer’s disease was admitted to residential care (3 participants), the person suffered from deteriorating physical health and cognition including hospitalization (1 participant), and the person passed away (1 participant, cause unrelated to the study). Only three of the control group did not return for the six-month assessment. Reasons that participants in the control group discontinued the programme were: the caregiver of one participant felt overwhelmed by the extra burden of the programme, the caregiver of another participant preferred the participant to be in the exercise programme, and a participant’s other health problems interfered. The combined drop-out rate of this pilot study was 27.5\%.
Reassessments occurred an average of 6.83 (SD = 1.27) months after baseline. Table 2 presents pre- and post-intervention scores for the outcome measures in the domains of falls and falls risk, balance and mobility performance, physical activity level, quality of life and caregiver burden of the exercise and control groups.

At reassessment, the falls rate/1000 person days (for the six-month intervention period) of the exercise group declined by approximately 33%, while
<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Exercise group</th>
<th>Control (education) group</th>
<th>IRR/OR (95% CI)</th>
<th>B coefficient (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Post-intervention</td>
<td>Baseline</td>
<td>Post-intervention</td>
<td>IRR = 0.997 (0.42−2.39)</td>
<td>OR = 1.110 (0.27−4.63)</td>
</tr>
<tr>
<td>Incidence rate of falls (in 1000 person-days)</td>
<td>4.61 ± 6.90</td>
<td>3.10 ± 4.27</td>
<td>1.30 ± 3.08</td>
<td>2.46 ± 4.05</td>
<td></td>
</tr>
<tr>
<td>Fallers: non-fallers, n (% fallers)</td>
<td>10:9 (52.6%)</td>
<td>9:10 (47.4%)</td>
<td>4:17 (19%)</td>
<td>7:14 (33.3%)</td>
<td></td>
</tr>
<tr>
<td>FROP-Com(^b) falls risk score</td>
<td>15.42 ± 4.99</td>
<td>14.37 ± 4.32</td>
<td>12.57 ± 5.56</td>
<td>16.47 ± 5.73</td>
<td></td>
</tr>
<tr>
<td>PPA(^c) score falls risk score</td>
<td>1.84 ± 1.18</td>
<td>1.86 ± 0.26</td>
<td>1.39 ± 1.21</td>
<td>1.81 ± 1.15</td>
<td></td>
</tr>
<tr>
<td>Functional Reach (cm)</td>
<td>23.51 ± 5.74</td>
<td>25.79 ± 5.56</td>
<td>28.48 ± 4.70</td>
<td>25.50 ± 5.33</td>
<td></td>
</tr>
<tr>
<td>Step Test (number of steps, worse side)</td>
<td>12.33 ± 2.38</td>
<td>12.28 ± 3.03</td>
<td>13.00 ± 3.23</td>
<td>11.81 ± 3.52</td>
<td></td>
</tr>
<tr>
<td>Timed Chair Stand (s)</td>
<td>13.16 ± 4.19</td>
<td>14.59 ± 5.10</td>
<td>13.26 ± 4.96</td>
<td>13.32 ± 3.73</td>
<td></td>
</tr>
<tr>
<td>Timed Up and Go (TUG) (s)</td>
<td>16.16 ± 4.96</td>
<td>16.18 ± 5.61</td>
<td>16.36 ± 6.62</td>
<td>16.55 ± 6.22</td>
<td></td>
</tr>
<tr>
<td>TUG (2nd task, manual task) (s)</td>
<td>18.44 ± 5.84</td>
<td>18.22 ± 6.59</td>
<td>18.03 ± 6.80</td>
<td>19.02 ± 7.31</td>
<td></td>
</tr>
<tr>
<td>TUG (2nd task, cognitive task) (s)</td>
<td>25.41 ± 7.97</td>
<td>23.20 ± 7.72</td>
<td>18.13 ± 3.36</td>
<td>19.15 ± 6.00</td>
<td></td>
</tr>
<tr>
<td>mCTSIB(^d) (sway velocity, degrees/s)</td>
<td>1.88 ± 0.73</td>
<td>1.83 ± 0.67</td>
<td>1.51 ± 0.73</td>
<td>1.68 ± 0.76</td>
<td></td>
</tr>
<tr>
<td>Limits of stability (LOS) (reaction time, ms)</td>
<td>1.17 ± 0.29</td>
<td>1.10 ± 0.19</td>
<td>1.17 ± 0.30</td>
<td>1.07 ± 0.20</td>
<td></td>
</tr>
<tr>
<td>LOS (movement velocity, degrees/s)</td>
<td>3.03 ± 1.30</td>
<td>2.98 ± 1.08</td>
<td>3.10 ± 1.15</td>
<td>3.41 ± 0.99</td>
<td></td>
</tr>
<tr>
<td>LOS (maximum excursion, % LOS)</td>
<td>66.32 ± 14.39</td>
<td>68.32 ± 15.45</td>
<td>72.40 ± 11.96</td>
<td>72.7 ± 12.13</td>
<td></td>
</tr>
<tr>
<td>LOS (directional control, %)</td>
<td>60.28 ± 12.33</td>
<td>60.67 ± 11.29</td>
<td>64.35 ± 9.94</td>
<td>61.32 ± 11.01</td>
<td></td>
</tr>
<tr>
<td>Walking (step width, cm)</td>
<td>16.23 ± 2.29</td>
<td>15.64 ± 2.49</td>
<td>15.56 ± 4.52</td>
<td>16.15 ± 3.97</td>
<td></td>
</tr>
<tr>
<td>Walking (step length, cm)</td>
<td>32.52 ± 8.29</td>
<td>31.79 ± 10.68</td>
<td>36.78 ± 13.18</td>
<td>36.03 ± 9.47</td>
<td></td>
</tr>
<tr>
<td>Walking (speed, cm/s)</td>
<td>39.39 ± 11.62</td>
<td>38.92 ± 13.55</td>
<td>40.43 ± 13.51</td>
<td>41.69 ± 13.33</td>
<td></td>
</tr>
<tr>
<td>Step quick turn (time, worse side, s)</td>
<td>3.81 ± 1.73</td>
<td>3.67 ± 1.96</td>
<td>3.32 ± 0.99</td>
<td>3.05 ± 1.06</td>
<td></td>
</tr>
<tr>
<td>Step quick turn (sway, worse side, degrees)</td>
<td>48.99 ± 11.06</td>
<td>48.46 ± 13.04</td>
<td>48.92 ± 8.22</td>
<td>47.30 ± 6.74</td>
<td></td>
</tr>
<tr>
<td>Sit to stand (raising index, % body weight)</td>
<td>13.50 ± 4.69</td>
<td>14.53 ± 6.11</td>
<td>16.32 ± 4.83</td>
<td>16.97 ± 6.86</td>
<td></td>
</tr>
<tr>
<td>Sit to stand (sway, degrees/s)</td>
<td>4.02 ± 1.14</td>
<td>4.29 ± 1.14</td>
<td>4.23 ± 1.28</td>
<td>4.67 ± 1.53</td>
<td></td>
</tr>
<tr>
<td>Human Activity Profile (adjusted score)</td>
<td>43.11 ± 13.61</td>
<td>42.05 ± 12.69</td>
<td>52.05 ± 14.65</td>
<td>49.52 ± 17.53</td>
<td></td>
</tr>
<tr>
<td>AQOL(^e) score</td>
<td>26.16 ± 4.86</td>
<td>25.63 ± 4.50</td>
<td>24.81 ± 4.64</td>
<td>25.43 ± 6.31</td>
<td></td>
</tr>
<tr>
<td>Caregivers' AQOL(^e) score</td>
<td>24.63 ± 4.29</td>
<td>25.12 ± 3.98</td>
<td>21.56 ± 4.37</td>
<td>21.53 ± 4.35</td>
<td></td>
</tr>
<tr>
<td>Caregivers' Zarit Burden score</td>
<td>24.44 ± 16.68</td>
<td>28.19 ± 17.43</td>
<td>24.50 ± 11.03</td>
<td>26.50 ± 11.56</td>
<td></td>
</tr>
</tbody>
</table>

\(^*\)P < 0.05; \(^**\)P < 0.01.

Test scores reported are mean and standard deviation.

\(^a\)The adjusted IRR, OR, B coefficient (95% confidence interval), and P-values are based on generalized linear models in which the exercise group is compared with the control group.

\(^b\)Falls Risk for Older People – Community (maximum score = 57, higher score means higher risk of falling).

\(^c\)Physiological Profile Assessment (short version) (higher score means higher risk of falling).

\(^d\)Modified Clinical Test of Sensory Interaction of Balance, static balance test on force platform.

\(^e\)Assessment of Quality of Life (maximum score = 60) (higher score implies poorer quality of life).
the control group increased by approximately 89% (Table 2). A similar pattern was seen in the change in proportion of fallers in the two groups, though neither of these between-group changes was significantly different.

Table 2 reports the change in outcome measures for both groups. There were significant improvements in the exercise group relative to the control group for the measures of Functional Reach and the Falls Risk for Older People – Community version (FROP-Com) score. There were also trends for greater improvement in the exercise group for the Step Test, the modified Clinical Test of Sensory Interaction of Balance (mCTISB) and the Timed Up and Go Test with dual (manual) task.

We also repeated the analyses using only complete cases (i.e. without imputation) and the results were similar to the results derived from the analyses of the imputed data set (data not reported).

**Safety, feasibility and adherence to the home-based exercise programme**

There were no falls or other serious adverse events associated with performing the exercise programme. Several participants, however, reported pain or discomfort when a new exercise was introduced. However, those symptoms either eased with continuing the exercises or were resolved by slight modification of the exercise by the physiotherapist.

At least two-thirds of the monthly exercise recording sheets were returned by each participant who completed the exercise programme. The average recorded adherence of the 11 participants was 82.96% (i.e. completing 82.96% of the recommended five sessions per week for the six-month period). Nine of the 11 participants had adherence >80%, with two having 100% adherence. Two participants had low adherence (21.56% and 65.18%). Reasons for low adherence for these two participants were unwillingness to undertake the exercise programme in one case, and the presence of another health condition in the other. All except one participant reported they intended to continue the exercises after the programme ceased.

For the education programme delivered by the occupational therapist, all participants participated in each of the six sessions provided.

**Discussion**

The results of this study suggest that a home-based balance, strengthening and walking exercise programme supervised by a physiotherapist can be implemented safely in people with mild to moderate Alzheimer’s disease, with no participants falling while carrying out the exercise programme. However, a higher number of participants in the exercise group discontinued the programme compared to the control programme. This might be explained by the different nature of the two programmes in which the exercise programme could be perceived as a more demanding programme than the more passive control programme, especially for the caregivers.

One-third of the participants who discontinued the exercises did so because of their caregivers’ health conditions, or because the caregivers were overwhelmed in managing other issues related to the participants’ Alzheimer’s disease, or other family member issues. These findings emphasize the important role caregivers play in supporting and encouraging people with Alzheimer’s disease to participate in an exercise programme. This supports previous studies that have shown that support from caregivers is an essential part of successful programme participation in people with cognitive impairment and/or with disability. Therefore, future clinical trials could involve an exercise education session for the caregivers, highlighting specifically what is required for participation, the goal of the programme and helpful strategies to supervise people with Alzheimer’s disease doing the exercise programme. These strategies may assist better participation in the programme.

For participants who completed the programme, a high level of adherence to the exercise programme was achieved. These findings indicate that caregivers or family members are often able to supervise and encourage people with Alzheimer’s disease to participate in a home exercise programme with a physiotherapist’s guidance and regular contact (either by phone calls or by visits).

Overall results from the study provide preliminary evidence that participants with mild to moderate Alzheimer’s disease may benefit from this type
of exercise programme. The findings indicate that the exercise programme can lead to a significant reduction in risk of falling (measured by FROPCom), as well as a significant improvement in dynamic standing balance (measured by the Functional Reach task). There were also trends for improvement (0.05 > P > 0.10) for the Step Test, Timed Up and Go Test (dual task) and a static sway measure (modified Clinical Test of Sensory Interaction of Balance). These findings are consistent with and add to the findings of the few previous studies reported in the review of the effectiveness of exercise programmes in people with dementia, which suggests that exercise programmes incorporating balance and/or strength training can reduce falls risk and improve balance and mobility performance in people with dementia.

In considering the benefits gained by participants in this study, we should recognize that the exercises were less intensive (approximately 15 minutes per exercise session or approximately 30 hours over the programme period) than those prescribed for participants in other exercise programmes for older people (approximately 30 minutes per exercise session or >50 hours over the programme period). The exercise sessions were less intense because of the effect of dementia on exercise participation – necessitating simple to perform exercises that did not incorporate high levels of cognition or attention. Furthermore, Alzheimer’s disease is a condition with degenerative progression and the length of duration between the baseline and follow-up assessment was approximately six months. Considering the above issues, the overall results of this study are encouraging and they provide some support for conducting a larger trial using the same intervention protocol.

This pilot study contributes to the literature because it is one of the few to have focused on the effects of an exercise programme for falls prevention specifically targeted for older people with Alzheimer’s disease living in the community. However, there are limitations of the study. The major limitation is the relatively small sample size recruited. This limitation reduced the power of the study to identify significant effects, however, even with the limited sample size, two significant improvements were observed, and trends were identified for improvement on several of the other balance- and mobility-related measures. This suggests that the effect of the intervention on these measures may be stronger than estimated in the a priori power calculations. A further limitation of the study is the potential bias in imputing missing data when the rate of missing data was relatively high and was different between the two groups. However, repeating analyses without missing data imputation did not change the findings of the study.

In summary, an individualized home-based balance, strengthening and walking exercise programme delivered by a physiotherapist appears to be safe and feasible for people with mild to moderate Alzheimer’s disease. Our findings indicate that the programme may improve or slow the deterioration in balance and mobility performance in people with Alzheimer’s disease. This is a modest beginning. A larger randomized controlled trial (post hoc sample size estimates indicated a sample of between 37 (Step Test) and 107 (Maximum Excursion) per group) is needed to clarify the effectiveness of the exercise programme in improving balance and physical performance and consequently in reducing the risk of falling in this population.

Clinical messages

- An individualized home-based balance, strengthening and walking exercise programme delivered by a physiotherapist is likely to be safe and feasible for people with Alzheimer’s disease who have daily support from a caregiver.
- Caregiver’s capacity to be involved with the programme should be taken into account when developing future exercise programmes for people with Alzheimer’s disease.

Disclosures

We certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on us or on any organization with which we are associated.
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Conflict of interest

The authors declare that there is no conflict of interest.

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